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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,424	04/21/2006	Seisuke Takashima	12480-000129/US	4236
30593 7590 12/04/2007 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,424	Applicant(s) TAKASHIMA ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :24 Jun 2005, 14 Jul 2005, 08 Nov 2005.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Japan 2002-381239, filed on 27 December 2002 has been received.
3. A certified copy of parent Application No. PCT/JP03/16284, filed on 18 December 2003 has been received.

Information Disclosure Statement

6. The information disclosure statements filed 24 June 2005, 14 July 2005 and 08 November 2005 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. A copy of the International Preliminary Examination Report as cited on all three IDS forms has not been received.

Specification

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that

the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

8. The abstract exceeds 150 words in length. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by White (US Patent 4,886,488).
11. Regarding claim 1, White discloses an aqueous humor drainage implant for draining aqueous humor in an eye to exterior of the conjunctiva for glaucoma treatment, comprising:
- a guiding tube part for guiding the aqueous humor to exterior of the eye (column 3, lines 42-48 and Figs. 1 and 4, tube 30); and

a filter part (column 4, lines 52-56, 65-68 and Fig. 4, microporous filter 40 comprising filter sheets 41, 42) connected to one end of the guiding tube part for preventing reflux infection from the exterior to interior of the eye,

wherein the guiding tube part includes:

an eye-side guiding part (column 3, lines 42-48 and Fig. 1, inlet end 31);

and

an outside-conjunctiva guiding tube part (column 3, lines 42-48 and Fig. 1, outlet end 32).

12. Regarding claim 2, White discloses an aqueous humor drainage implant wherein the outside-conjunctiva guiding tube part has an outer diameter smaller than an inner diameter of the nasolacrimal duct (column 3, lines 37-48 and Fig. 1, tube 30 within nasolacrimal duct 24).

13. Regarding claim 3, White discloses an aqueous humor drainage implant wherein the outside-conjunctiva guiding tube part and the filter part are shaped to have a curved outer surface and sized to have substantially the same outer diameter (Fig. 1, both ends of tube 30 depicted as having substantially same outer diameter).

Claim Rejections - 35 USC § 102 / 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over White (US Patent 4,886,488).

17. Regarding claim 7, White discloses an aqueous humor drainage implant wherein the outside-conjunctiva guiding tube part has a flexural modulus of no greater than 2000 Mpa at ordinary temperature (column 3, lines 55-58).

When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, having an outside-conjunctiva guiding tube part) except for a property or function (in the present case, having a flexural modulus of no greater than 2000 Mpa at ordinary temperature) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicant discloses forming the implant tubes from "...various types of polymer materials, including: silicone resins; polyolefin resins such as polyethylene, polypropylene, polyisobutylene, ethylene-vinyl acetate copolymer, and polynorbornene; polyurethane resins; natural rubbers; and synthetic rubbers" (specification, pages 26-27). White discloses forming an entire length of tube 30 from silicone or polyethylene, the same materials disclosed in the immediate specification. Therefore, the materials used by White are capable of having a flexural modulus of no greater than 2000 Mpa at ordinary temperature (column 3, lines 55-58) as claimed [claim 7].

18. Regarding claim 8, White discloses an aqueous humor drainage implant wherein the outside-conjunctiva guiding tube part includes:

an outside-conjunctiva eye-side guiding tube part and an outside-conjunctiva filter-side guiding tube part (column 3, lines 42-48, portions of tube 30 within eye and adjacent microporous filter 40),

wherein the outside-conjunctiva eye-side guiding tube part and the outside-conjunctiva filter-side guiding tube part are connected to each other portions of tube 30 substantially adjacent), and

wherein the outside-conjunctiva eye-side guiding tube part has a smaller flexural modulus than the outside-conjunctiva filter-side guiding tube part at ordinary temperature (column 3, lines 51-55, end portions of tube 30 formed of different material than tube body). Silicone is disclosed as having a flexural modulus of 207 to 248 MPa (online material property listing of silicone), while PMMA is disclosed as having a flexural modulus of 3.138GPa, or 3138 MPa (online material property listing of PMMA).

Since White discloses a tube having a length comprising silicone and ends optionally comprising PMMA, White substantially discloses a filter-side part having a smaller flexural modulus. The degree of an "end" is not disclosed in the White reference. In other words, the invention of White is substantially capable of having portions of both increased and decreased flexural moduli on an eye-side or filter-side. Regarding rationale, see discussion of claim 7 above.

Claim Rejections - 35 USC § 103

19. Claims 4, 5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US Patent 4,886,488) in view of Brown (US Patent Application Publication No. 2002/0169468).

20. Regarding claims 4 and 5, White discloses the invention as substantially claimed. See above. However, White lacks a chemically bound anionic group or cationic group, and wherein the guiding tube part and the filter part are rendered hydrophilic as claimed [claims 4 and 5]. Brown discloses a guiding tube part and filter part including a chemically bound cationic group (paragraph [0034], surfaces of device including filter coated with phosphorylcholine). Phosphorylcholine contains a cationic group (see online chemical dictionary). Brown provides the advantage of reducing protein plugging in a filter (paragraph [0034]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of White as discussed with the chemically bound cationic group as taught by Brown in order to reduce protein plugging.

21. Regarding claim 9, White discloses the invention as substantially claimed. See above. However, White lacks an aqueous humor drainage implant wherein the filter part includes a hollow fiber membrane made of at least one kind of polymer material selected from the group consisting of a polyolefin polymer, a polyvinyl alcohol polymer, an ethylene-vinyl alcohol copolymer, a polysulfone polymer, a polyacrylonitrile polymer, a cellulose polymer, cellulose acetate polymer, a polymethyl methacrylate polymer, and a polyamide polymer as claimed [claim 9]. White is silent regarding the material of microporous filter 40.

Brown discloses filter part includes a hollow fiber membrane made of polyacrylonitrile polymer (paragraph [0044]). Brown provides the advantage of a filter material that is biocompatible, non-degradable and immunoisolating (paragraph [0041]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of White as discussed with the filter material as taught by Brown in order to provide a biocompatible, non-degradable and immunoisolating filter material.

22. Regarding claims 10 and 11, White discloses the invention as substantially claimed. See above. However, White lacks an average filter pore diameter of no greater than 0.3 μm and 0.02 μm as claimed [claims 10 and 11]. Brown discloses an aqueous humor drainage implant wherein the hollow fiber membrane has an average pore diameter of no greater than 0.3 μm (paragraph [0011], micropores having diameter less than or equal to about 0.2 μm). Brown further discloses micropores having an average pore diameter approximately 0.02 μm (paragraph [0042]). Brown provides the

advantage of preventing ingress of bacteria (paragraph [0037]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of White as discussed with the average pore diameter as taught by Brown in order to prevent bacteria ingress.

23. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over White (US Patent 4,886,488) in view of Camras (US Patent 5,346,464).

24. Regarding claim 6, White discloses the invention as substantially claimed. See above. However, White lacks a joint part for detachably connecting the eye-side guiding tube part and the outside-conjunctiva guiding tube part as claimed [claim 6]. Camras discloses a joint part for detachably connecting parts of an ocular implant (column 3, lines 59-68 through column 4, lines 1-8 and Fig. 6, portions 16a' and 14b' coupled to sleeve 30). Camras provides the advantage of allowing an implant to be implanted in parts, and then assembled. This avoids a more complicated surgery which would require implanting an entire device into the eye at once. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of White as discussed with the joint part as taught by Camras in order to simplify surgical manipulation.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Cote et al. (WO 01/50943)
- ❖ Lippman (US Patent 5,073,163)
- ❖ L'Esperance, Jr. (US Patent 5,300,020)
- ❖ Richter et al. (US Patent 5,702,414)
- ❖ Jacob (US Patent 5,882,327)
- ❖ Tu et al. (US Patent Application Publication No. 2002/0143284)
- ❖ Allan et al. (US Patent 6,186,974)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761

Adam Marcetich

AMM

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

Tatyana Zalukaeva